



# Instructions for Use and Owner's Manual



## **International Biophysics Corporation**

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Austin. TX 78744

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**[AffloVest.com](http://AffloVest.com)**

Dear Customer,

Congratulations on your purchase of an AffloVest! We are excited to bring you a new level of freedom while complying with the therapeutic requirements of your health professional. Thank you for placing your trust with us. To ensure that you derive maximum benefit from the AffloVest and to ensure your safety, please familiarize yourself with the information in this AffloVest User Manual.

The AffloVest User Manual contains important SAFETY and TECHNICAL DATA. Please keep this manual in a safe place for easy reference.

With proper care and maintenance, the AffloVest will reward you with a long, trouble-free service life. We greatly value the satisfaction of our Customers and hope you are completely satisfied with your AffloVest by International Biophysics Corporation.

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## EXPLANATION OF SYMBOLS

### Test and Identification Symbols - AffloVest



TÜV Symbol - A Tested Medical Product



CE Mark - A European Conformity Symbol for Medical Products - Designated body Berlin Cert; Body Floating (Not Grounded/Earthed)



Direct Current (DC Power)



Alternating Current (AC Power)

### Test and Identification Symbols - Battery Wall Charger, AC Power Adapter and DC Battery Charger



TÜV Rheinland Approval - In Accordance with EN60601-1 and IEC 60601-1



Communauté Européenne (European Community) - Directives governing electrical and electronic devices



FCC is the American Test Symbol for Electromagnetic Compatibility, issued by the Federal Communications Commission



Recognized Component Mark - American Test Symbol for American and Canadian Markets

### Test and Identification Symbols - Rechargeable Battery



Recycling Symbol



Electronic Scrap - Do not Dispose of in Household Waste



Communauté Européenne (European Community) - Directives governing electrical and electronic devices



Attention! Read Operating Instructions Before Use!



Do Not Short-Circuit!



Do Not Place Near Or Into Fire!



Do Not Submerge In Water!

## TECHNICAL DATA

Nominal Voltage:	12V DV
Nominal Power Consumption:	Approx. 30W
Battery Wall Charger:	INPUT: 100-240V AC / 50/60 Hz OUTPUT: 12V DC / 1.20 A
A/C Power Adapter:	INPUT: 100-240V AC / 50/60 Hz OUTPUT: 12V DC / 8.33 A
DC Battery Charger:	INPUT CONNECTOR: Standard 12V DC Cigarette Lighter Plug  OUTPUT CONNECTOR: 2.5mm x 5.5mm DC Plug
Lithium-ion Battery:	OUTPUT: 12V/2.5 Ah
Manufacturer / Distributor:	International Biophysics Corporation 2101 E. St. Elmo Road, Building 2, Suite 275 Austin, TX 78744
Sizes:	XS (Extra Small) S (Small) M (Medium) L (Large) XL (Extra Large) XXL (Extra Extra Large)

## USER INFORMATION

### IMPORTANT!

The AffloVest should be worn over clothing or with a fabric shield to prevent cross-contamination in a clinic or hospital setting where more than one patient uses the unit. The AffloVest should be cleaned appropriately between patient use, utilizing a disinfecting cleaning solution or wipes.

According to the American Association for Respiratory Care (AARC) Guidelines for Postural Drainage Therapy, the decision to use the unit for Airway Clearance Therapy requires careful consideration and a doctor's assessment of the individual patient's case if the following conditions exist:

- Intracranial pressure (ICP) greater than 20 mm Hg
- Recent spinal surgery or acute spinal injury
- Bronchopleural fistula
- Pulmonary edema associated with congestive heart failure
- Large pleural effusions or empyema
- Pulmonary embolism
- Acute illness
- Pregnancy or nursing mothers
- Electronic implants
- Rib fractures, with or without flail chest
- Surgical wound or healing tissue or recent skin grafts or flaps on the thorax
- Uncontrolled hypertension
- Distended abdomen
- Recent esophageal surgery
- Active or recent gross hemoptysis
- Uncontrolled airway at risk for aspiration such as tube feeding or a recent meal
- Subcutaneous emphysema
- Recent epidural spinal infusion or spinal anesthesia
- Burns, open wounds, and skin infections on the thorax
- Recent placement of transvenous or subcutaneous pacemaker
- Suspected pulmonary tuberculosis
- Lung contusion
- Bronchospasm
- Osteoporosis or osteomyelitis of the ribs
- Coagulopathy
- Complaint of chest wall pain

## INDICATIONS FOR USE/METHOD/APPLICATION

### INDICATIONS FOR USE

The AffloVest is intended for promoting airway clearance and improvement of bronchial drainage by enhancing mobilization of bronchial secretions where external manipulation of the thorax is the physician's choice of treatment.

### METHOD

The AffloVest generates vibration and oscillation of the user's chest wall through integrated motor modules, installed into various parts of the vest. The patient controls the rate and frequency at which these motors oscillate the thoracic region with the use of a controller attached to the vest that can increase

or decrease intensity to address the volume of mucus present in the air pathways, in compliance with a physician's prescription and orders.

### APPLICATION

The AffloVest can be used, per a physician's prescription, in the treatment of a variety of conditions and diseases, including genetic, neuromuscular and immunological disorders causing chronically compromised airway clearance. Among the most common are cystic fibrosis, cerebral palsy, bronchiectasis, ALS, Muscular Dystrophy and Multiple Sclerosis.

## UNPACKING AND USING THE AFFLOVEST FOR THE FIRST TIME

### ATTENTION!

- Please follow the STEPS in order to ensure proper set-up.
- Battery must be fully charged before use (this is covered in the STEPS below).

### PACKAGE CONTENTS



AffloVest



Rechargeable Battery  
(Lithium-ion)



AC Power Adapter



Carrying Case



Battery Wall Charger



Owner's Manual



DC Battery Charger



Warranty

## STEP 1 – UNPACKING THE AFFLOVEST

Carefully unpack the AffloVest and its accessories.

**You must fully charge the battery before proceeding to STEP 3.**

## STEP 2 - CHARGING THE BATTERY FOR THE FIRST TIME

- Use only the supplied rechargeable battery and the supplied battery wall charger to ensure safe and reliable operation of the AffloVest in battery mode.
- The battery must be fully charged before using the AffloVest for the first time.
- To charge the battery, connect it to the battery wall charger unit. The charging time is approximately 3-4 hours.
  - » *When charging, the Red LED on the battery wall charger will illuminate.*
  - » *When fully charged, the Red LED on the battery wall charger changes to Green.*
  - » *To check the battery charge level, press and hold the round button on the battery. The 4 LEDs flash once, then the charge level is displayed. When fully charged, the 4 LED lights on the battery will remain on after the initial flash. If the battery is partially drained, the 4 LEDs will flash once, then the charge level will be displayed. Please note that the LED indicators on the battery are for general reference only and should not be used to determine whether the battery is fully charged. Use the battery wall charger Red/Green indicator for this determination.*
- When the battery wall charger LED changes from Red to Green unplug the battery wall charger and proceed to the next STEP **Do not connect the battery to the AffloVest yet.**

## STEP 3 – CONNECTING THE CONTROLLER TO THE AFFLOVEST

- Insert the hand-held controller into its pocket on the left side of the AffloVest.
- Carefully align and plug the controller connector into the cable coming from the AffloVest.
- Make sure the controller cable connectors are fully inserted into one another.



## STEP 4 – CONNECTING THE BATTERY TO THE AFFLOVEST

- Insert the **fully charged** battery into its pocket on the right side of the AffloVest and connect it to the power cable coming from the vest. Make note of the LEDs on the hand-held controller as you plug in the battery.
  - » *When the fully charged battery is initially plugged into the AffloVest, all the lights on hand-held controller unit will flash, after which the "OFF" LED will blink steadily for approximately 7 minutes, indicating that the battery has been recognized and is ready to operate the AffloVest. The AffloVest can be used immediately once the battery is recognized – You do not have to wait for "OFF" LED to stop blinking.*
- Make sure the battery power cable connector is fully inserted into the battery.

## YOUR AFFLOVEST IS NOW READY FOR USE!

### IMPORTANT!

- To ensure maximum intensity throughout treatment time, press and hold the battery button before starting a treatment. If only one of the four battery LEDs flashes on, it is recommended that the battery be fully recharged before starting treatment.
- The battery must be charged when only one of the four battery LEDs illuminates when the battery button is pressed.
- Unplug the battery from the AffloVest after treatment to avoid draining the battery.
- Unplug the battery wall charger from outlet when not in use.
- If the battery has not been used for over 30 days, please check the charge level before use and recharge if necessary.

## FITTING THE AFFLOVEST AND ACTIVATING A TREATMENT CYCLE

- Unbuckle the chest buckles on the AffloVest and set the buckles to maximum size.
  - Put on the AffloVest and fasten all 3 buckles. Firmly pull the buckle straps so that the vest fits snugly on the body, but does not restrict a deep, full breath. Pull evenly on the straps located on each side of the buckles until there is only an approximate 1" to 5" gap between the two sides of the AffloVest.
  - Adjust the shoulder snaps to place the front upper AffloVest motors on the upper chest just below the collar bone.
  - Select treatment program by pressing the **P1-DRAINAGE, P2-VIBRATION, OR P3-PERCUSSION** button. The AffloVest will start operating about 2 seconds after you press the button.
  - **INTENSITY** settings may now be selected.
- the wall.
- All the LEDs on the controller will flash, after which the "OFF" LED will continue to blink, indicating that the AffloVest is ready for use.
  - Select treatment program by pressing the **P1-DRAINAGE, P2-VIBRATION, OR P3-PERCUSSION** button. The AffloVest will start operating in about 2 seconds.
  - **PROGRAM** and **INTENSITY** settings may now be selected.

### AC AND DC ADAPTERS

- AC Power Adapter – will operate the AffloVest from a wall outlet.
- Battery Wall Charger – will charge the AffloVest battery from a wall outlet.
- DC Battery Charger – will charge the AffloVest battery using DC current from a vehicle power outlet. You cannot operate the AffloVest using the DC battery charger.
- Power consumption is approximately 30 Watts.
- Designed for use with AC voltage of 100-240V AC, 50/60Hz.

### USING THE AFFLOVEST IN AC MODE WITH THE AC POWER ADAPTER

- Disconnect the AffloVest power cable from the battery and connect it to the supplied AC power adapter.
- Connect the AC power adapter cord first into the black charging block, then into

## WHEN TO CLEAN THE AFFLOVEST

- When the AffloVest becomes visibly soiled, and also between patient uses in multi-patient care environments, we recommend sanitizing the AffloVest.
- In a single-user environment; it is recommended that the AffloVest be cleaned monthly.

## CLEANING THE AFFLOVEST

To clean the AffloVest, please utilize a broad-spectrum disinfecting wipe rated to kill at least 99.9% of bacteria and viruses and follow the manufacturer's instructions for use. Using appropriate protective equipment, including disposable latex-free gloves, follow the instructions below to clean the AffloVest using the disinfecting wipes.

- 1) Unplug the AffloVest, if plugged into an electrical outlet.
- 2) Unbuckle battery and controller flaps
  - a. Disconnect and remove battery from AffloVest pouch
  - b. Disconnect and remove controller from AffloVest pouch
- 3) Unbuckle front buckles and shoulder snaps and lay AffloVest flat so that the inside of AffloVest is exposed
  - a. Wipe the outer edges of the AffloVest, starting in the collar area, tracing the outer edges all the way around the AffloVest and repeat.
  - b. Wipe all exposed fabric thoroughly, pressing into creased areas, and repeat.
- 4) Turn AffloVest over and lay it flat
  - a. Starting at the top, wipe the exposed AffloVest fabric thoroughly, pressing into creased areas, and repeat.
- 5) Wipe battery thoroughly.
- 6) Wipe controller thoroughly.
- 7) Wipe all accessories thoroughly including all cables.
- 8) Wipe carry case thoroughly (inside and outside).
- b. Wipe male and female snaps.
- c. Wipe buckles and straps on each side.
  - i. Make sure to wipe inside female connector of buckle.
  - ii. Make sure to wipe ridges on male connector of buckles.
- d. Wipe battery flap and the inside and outside of battery pouch.
- e. Wipe battery cable protruding from AffloVest.
- f. Wipe controller flap and the inside and outside of controller pouch.
- g. Wipe controller cable protruding from AffloVest.

## CLEANING AND CARE WARNINGS

- Not machine washable.
- Do not submerge or immerse the AffloVest or any of its accessories, as permanent damage or electrical shock may result.
- Do not use bleach or a cleaner containing bleach.

## CLEANING AND CARE INFORMATION SYMBOLS



Do Not Iron!



Do Not Bleach!



Do Not Machine Wash!



Do Not Submerge!



Do Not Tumble Dry!

## SAFETY FEATURES

- The AffloVest was designed with maximum safety in mind, therefore it contains the following safety features:
  - » *Motor modules operate at safe, low voltages.*
  - » *The Controller contains a fuse in the event of electrical problems.*
  - » *The Controller operates on a timer to ensure shut-off.*

## BUTTONS AND FUNCTIONS

### PROGRAM AND INTENSITY LEVELS

- Press the **P3 button to start the PERCUSSION program**. All motors operate in a pulsating/tapping on/off mode, providing the upper body with a regular, percussive rhythm.
- Press the **P2 button to start the VIBRATION program**. All motors operate uniformly at the set intensity level, providing deep oscillation of the thoracic cavity.
- Press the **P1 button to start the DRAINAGE program**. The individual zones are activated in succession, with the oscillation traveling up and down the thoracic cavity.
- When starting P1, P2 or P3, the motors run through a “soft start” function (approximately 10 seconds), then ramp-up to the set level of intensity.
- Programs P1, P2 and P3 always start in the SOFT intensity level. **You may change the intensity level to SOFT, MEDIUM, or INTENSE once the AffloVest has begun to operate.**

### PLEASE NOTE!

- The intensity automatically switches to SOFT when switching between P1, P2 and P3 programs. The intensity level can then be changed as desired to SOFT, MEDIUM or INTENSE.
- Each P1, P2 or P3 program will run for approximately 8 minutes (+/- 1 minute), after which the AffloVest will shut off. When changing between the P1, P2 or P3 programs, the new program selected will run for approximately 8 minutes (+/- 1 minute).
- You can stop the operation of the AffloVest at any time by pressing the STOP button. Doing so will reset the timer so that the 8 minute cycle starts over again when the AffloVest is activated.
- The controller will switch to standby mode about 7 minutes after the program has ended or been stopped and the LED lights on the hand-held controller will go out.
- The AffloVest can be reactivated by pressing any button, then press either P1, P2 or P3 to start the Afflovest.
- The LED lights 1-5 on the hand-held controller show which oscillation zones are currently active.
- The LED lights P1, P2 or P3 on the hand-held controller show which P1, P2 or P3 program is active.
- When the “OFF” LED blinks on and off, this indicates that the AffloVest is ready for operation.
- When the “OFF” LED is lit continuously, this indicates that the AffloVest is operating normally in the selected program.



## TURNING OFF THE AFFLOVEST

The AffloVest can be stopped at any time by pressing the **STOP** button. All programs are terminated and the flashing "OFF" LED indicates that the AffloVest is active and awaiting input. After about 7 minutes, the "OFF" LED will go out and the AffloVest will enter standby mode.

## BATTERY WARNING INFORMATION

- The battery must never be thrown into a fire or incinerated.
- The battery must not be immersed in liquids, such as water, sea water, or beverages. Contact with liquids must be avoided.
- The battery is not a toy and must be kept away from young children and babies.
- The battery must not be placed in a microwave or subjected to pressure. It may combust, resulting in smoke and fire.
- The battery must not be dropped onto a hard surface.
- Never dismantle the battery, as this may cause internal short-circuits, resulting in gas emissions, fire and explosion, or other problems.
- The electrolytes and electrolyte vapors contained within the case of lithium-ion batteries may be harmful to humans. **DO NOT ATTEMPT TO OPEN THE BATTERY CASE.** If the battery case breaks or is compromised, avoid direct contact with the electrolytes within. If electrolytes come in contact with the skin, eyes or other parts of the body, immediately flush or rinse with fresh water and seek medical attention as soon as possible.
- Store battery on a non-combustible, heat resistant and non-conductive surface.
- Do not expose the battery to direct sunlight.
- The maximum permissible ambient temperature of the battery is 120° F degrees.

## SAFETY INFORMATION

The AffloVest is certified with the standard EN 60601 and corresponds to the Medical Devices Directive 93/42EEC:

THE MANUFACTURER, **INTERNATIONAL BIOPHYSICS CORPORATION**, SHALL ACCEPT NO LIABILITY WHATSOEVER FOR ANY DAMAGE AND/OR CONSEQUENTIAL DAMAGE RESULTING FROM NON-COMPLIANCE WITH THE FOLLOWING SAFETY INFORMATION.

- Repairs to the AffloVest or its electrical components may only be carried out by International Biophysics Corporation authorized electricians or service dealers. Unauthorized repairs will void the AffloVest warranty and may place the user at considerable risk or damage the AffloVest.
- The AffloVest has 2 zippers with gold tags, one on either side of the AffloVest. **DO NOT OPEN THESE ZIPPERS.** Tampering with or opening these zippers will void the AffloVest Warranty.

THE MANUFACTURER, **INTERNATIONAL BIOPHYSICS CORPORATION**, SHALL NOT BE LIABLE FOR ANY DAMAGE AS A RESULT OF: 1) THE AFFLOVEST BEING USED FOR ANYTHING OTHER THAN ITS INTENDED PURPOSE, 2) INCORRECT USE, OR 3) IMPROPER REPAIR RESULTING FROM HAVING THE AFFLOVEST REPAIRED BY ANYONE THAT IS NOT AN INTERNATIONAL BIOPHYSICS CORPORATION AUTHORIZED REPAIR FACILITY OR TECHNICIAN.

- The AffloVest may only be used with the AC power adapter and the rechargeable battery .
- The battery may only be charged with the supplied battery wall charger or DC battery charger units in accordance with these instructions. The use of any other power supply units or chargers may lead to fire and electric shock and will void the AffloVest Warranty.
- Never store the AffloVest in temperatures exceeding 100° F.
- Pay attention to the voltage ratings on the power supply unit.  
The AffloVest is designed for use with AC voltage of 100-240V AC, 50/60Hz.  
The AC power adapter and battery wall charger are intended for use within the ambient temperature range of 32° F – 120° F degrees.
- Always unplug the AffloVest when not in use.
- Unplug the AC power adapter if the AffloVest malfunctions while powered by AC current.
- Always unplug the AffloVest from AC current, and remove the battery and the hand-held controller before cleaning with any type of liquid disinfectant or cleaning solution.
- Never disconnect the power plug from an electrical outlet with wet hands.
- Never pull the AffloVest power cords or cable over sharp edges or allow them to kink or bind.
- Periodically check the AffloVest, its accessories and its cords and cables for damage. If you have questions about damage, contact your AffloVest dealer.
- Use only the power cables supplied with the AffloVest.
- Never carry or lift the AffloVest by any of its electrical cables or components.
- Children and disabled persons should not use the AffloVest without supervision.
- Do not use the AffloVest in damp environments, such as in the bathroom or at a swimming pool. Do not puncture the AffloVest with sharp objects, such as pins or needles.

## ENVIRONMENTAL PROTECTION



This symbol, on products and/or accompanying documents, signifies that electrical and electronic products must be disposed of separately from any household waste at the end of their service. To ensure that these products are recycled effectively, deposit them at municipal collection points for recyclable materials where they will be accepted free of charge.

Correct disposal of products will help protect the environment and avoid harmful effects to human beings and the environment that may arise from incorrectly handling devices at the end of their service life. You can obtain more detailed information at the nearest collection point for recyclable materials in your area.

## TRAVELING WITH LITHIUM-ION BATTERIES

Lithium-ion batteries can be considered hazardous by the FAA. Familiarize yourself with any travel guidelines before you travel. Contact your carrier or visit their website for guidance.





TROUBLESHOOTING

IMPORTANT

Before attempting any troubleshooting, ensure that the battery is fully charged. To check the battery charge level, connect the battery to the Battery Wall Charger and plug the charger into a wall outlet. Wait 30 seconds. If the indicator on the Battery Wall Charger is GREEN, the battery is fully charged. If the indicator is RED, allow the battery to charge until the indicator turns GREEN. The LEDs on the battery itself are used as a reference only and may not indicate “full charge” accurately.

SYMPTOM	POSSIBLE CAUSE	TROUBLESHOOTING STEPS
<p>AffloVest will not activate with a charged battery (“OFF” LED light on controller does not blink when battery is connected to the AffloVest.)</p> <p><b>OR</b></p> <p>AffloVest will not activate when connected to AC Power Adapter (“OFF” LED light on controller does not blink when the AffloVest is connected to the AC Power Adapter, and the AC Power Adapter is plugged into the wall.)</p>	<p>Power is possibly not being supplied properly to the AffloVest.</p> <p><b>OR</b></p> <p>Possible damaged controller.</p> <p><b>OR</b></p> <p>Possible damaged battery.</p>	<ol style="list-style-type: none"> <li>Verify that the battery is fully charged per the instructions above.</li> <li>Completely disconnect and reconnect the controller connector, making sure the connector is fully inserted and seated correctly. (Try to turn AffloVest on by pressing a “P” button. If it will not activate, continue to the next step.)</li> <li>Check the controller to see if the “STOP” button is stuck down. Press the “STOP” button in an attempt to unstick. (Try to turn AffloVest on by pressing a “P” button. If it will not activate, continue to the next step.)</li> <li>Disconnect the battery from AffloVest completely and wait 15 seconds. Next, connect the battery to AffloVest, ensuring that the battery connector is fully inserted and seated correctly. See if the “OFF” LED light on the controller is now blinking. If it is blinking, press a “P” button to activate AffloVest. If the “OFF” LED light is not blinking or AffloVest will not power up, continue on to the next step.</li> <li>Disconnect the battery from AffloVest. Connect AffloVest to the AC Power Adapter and plug the adapter into a wall outlet. Make sure both connections are seated correctly. Observe to see if the “OFF” LED light on the controller is now blinking. If it still does not blink, contact your dealer to arrange for further assistance.</li> <li>If AffloVest functions properly on AC power, but the fully charged battery could not be recognized by the controller, contact your dealer to report the battery problem and arrange for further assistance.</li> </ol>

SYMPTOM	POSSIBLE CAUSE	TROUBLESHOOTING STEPS
<p>AffloVest will not activate after an extended period of non-use.</p>	<p>AffloVest electronics have entered “inactive” mode.</p>	<ul style="list-style-type: none"><li>• Disconnect the battery and controller, wait 3 seconds and reconnect battery and controller.</li></ul>
<p>The selected program function has suddenly switched off.</p>	<p>The therapy cycle has finished and a new therapy cycle must be started.</p> <p><b>OR</b></p> <p>Battery discharged.</p>	<ul style="list-style-type: none"><li>• Start a new therapy cycle.</li><li>• Charge battery or switch to the AC Power Adapter.</li></ul>
<p>AffloVest won’t shut off.</p> <p><b>OR</b></p> <p>Automatically turns on.</p>	<p>Stuck button on controller.</p>	<ul style="list-style-type: none"><li>• Press each button on the controller in an attempt to unstick the button. If you cycle through all the buttons 3 times or more and the problem is not resolved, contact your dealer for further assistance.</li></ul>

ELECTROMAGNETIC GUIDELINES FOR CLINICAL APPLICATIONS

The AffloVest is intended for use in the electromagnetic environment specified below.  
The customer or user of the AffloVest should ensure that it is used in such an environment.

EMITTED INTERFERENCE MEASUREMENT	CONFORMITY	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
RF emissions as per CISPR 11	Class B	The AffloVest is suitable for use in all establishments, including domestic, and those directly connected to the public power supply network that supplies buildings used for domestic purposes.
Harmonic component emissions as per IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions as per IEC 61000-3-2	Compliant	

The AffloVest is intended for use in the electromagnetic environment specified below.  
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INTERFERENCE IMMUNITY TESTS	IEC 60601-TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
Electrostatic discharge (ESD) as per IEC 61000-4-2	<ul style="list-style-type: none"> <li>• ±6 kV Contact Discharge</li> <li>• ±8 kV Air Discharge</li> </ul>	<ul style="list-style-type: none"> <li>• ±6 kV Contact Discharge</li> <li>• ±8 kV Air Discharge</li> </ul>	<ul style="list-style-type: none"> <li>• Floors should be wood, concrete, or ceramic tile. If floors are covered with a synthetic material, the relative humidity should be at least 30%</li> </ul>
Fast Electrical Transients/Bursts as per IEC 61000-4-4	<ul style="list-style-type: none"> <li>• ±2 kV for Power Supply Lines</li> <li>• ±1 kV for Input/Output</li> <li>• Lines</li> </ul>	<ul style="list-style-type: none"> <li>• ±2 kV for Power Supply Lines</li> <li>• ±1 kV for Input/Output Lines</li> </ul>	<ul style="list-style-type: none"> <li>• Mains power quality should be that of a typical commercial or hospital environment</li> </ul>
Surge Voltages (Surge) as per IEC 61000-4-5	<ul style="list-style-type: none"> <li>• ±1 kV Normal-Mode Voltage</li> <li>• ±2 kV Common-Mode</li> <li>• Voltage</li> </ul>	<ul style="list-style-type: none"> <li>• ±1 kV Normal-Mode Voltage</li> <li>• ±2 kV Common-Mode Voltage</li> </ul>	<ul style="list-style-type: none"> <li>• Mains power quality should be that of a typical commercial or hospital environment</li> </ul>
EVoltage Dips, Short-Term Interruptions and Fluctuations in Supply Voltage as per IEC 61000-4-11	<ul style="list-style-type: none"> <li>• &lt;5% Ut (&gt;95% dip in Ut) for 0.5 cycle</li> <li>• 40% Ut (60% dip in Ut) for 5 cycles</li> <li>• 0% Ut (30% dip in Ut for 25 cycles</li> <li>• &lt;5% Ut (&gt;95% dip Ut for 5 s</li> </ul>	<ul style="list-style-type: none"> <li>• &lt;5% Ut (&gt;95% dip in Ut) for 0.5 cycle</li> <li>• 40% Ut (60% dip in Ut) for 5 cycles</li> <li>• 0% Ut (30% dip in Ut) for 25 cycles</li> <li>• &lt;5% Ut (&gt;95% dip Ut) for 5 s</li> </ul>	<ul style="list-style-type: none"> <li>• Mains power quality should be that of a typical commercial or hospital environment. If the user of the AffloVest requires continued operation during interruptions in the power supply, it is recommended that the AffloVest be powered from an uninterruptible power supply or battery</li> </ul>
Power Frequency (50 Hz) Magnetic Field as per IEC 61000-4-8	<ul style="list-style-type: none"> <li>• 3 A/m</li> </ul>	<ul style="list-style-type: none"> <li>• 3 A/m</li> </ul>	<ul style="list-style-type: none"> <li>• Power frequency magnetic fields should be at levels characteristic of a location in a commercial or hospital environment</li> </ul>

NOTE: Ut is the mains AC voltage prior to application of the test level.

The AffloVest is intended for use in the electromagnetic environment specified below.  
 The customer or user of the AffloVest should ensure that it is used in such an environment.

INTERFERENCE IMMUNITY TESTS	IEC 60601-TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
Conducted RF interference as per IEC 61000-4-6	3 V <sub>rms</sub> 150 kHz to 80 MHz	3 V <sub>rms</sub>	<ul style="list-style-type: none"> <li>• Portable and mobile RF communications equipment should be used no closer to any part of the AffloVest, including the cables, than the recommended distance calculated from the equation applicable to the transmit frequency.</li> <li>• Recommended distance: d = 1.2 m P</li> <li>• d=1.2 m P for 80 MHz to 800 MHz d=2.3 m P for 800 MHz to 2.5 GHz</li> <li>• Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended distance in meters (m). The field strength of fixed RF transmitters, as determined by an electromagnetic site survey(a) should be less than the compliance level in each frequency range(b). Interference may occur in the vicinity of equipment marked with the following symbol.</li> </ul>
Radiated RF interference as per IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3 V/m	

NOTE 1: The higher frequency range applies at 80 MHz and 800 MHz.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and persons.

- (a) The field strength from fixed transmitters, such as base stations for radio telephones and mobile terrestrial radio equipment, amateur radio stations, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment in terms of fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AffloVest is used exceeds the applicable compliance level specified above, the AffloVest should be observed to verify normal operation. If abnormal performance features are observed, additional measures may be necessary, such as re-orienting or relocating the AffloVest.
- (b) The field strength should be less than 3 V/m over the frequency range from 150 kHz to 80 MHz.

Recommended distances between portable and mobile RF telecommunications equipment and the AffloVest.

The AffloVest is intended for use in an electromagnetic environment, in which RF interference is controlled. The customer or user of the AffloVest can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the AffloVest as recommended below - dependent on the maximum output power of the communications equipment.

Nominal Transmitter Output (W)	Distance Dependent on Transmit Frequency (m)		
	150 kHz to 80 MHz d = 1.2 m P	80 MHz to 800 MHz d = 1.2 m P	800 MHz to 2.5 GHz d = 2.3 m P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

The recommended distance d in meters (m) for transmitters with a maximum nominal output not specified in the table above can be calculated using the equation applicable to the transmitter frequency (in the specific column in the table), where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: The higher frequency range applies at 80 MHz and 800 MHz.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, object and persons.

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